K071952

510(k) SUMMARY

GraftLok™ Screw
GraftLok™ ST Screw

AUG 14 2007

Applicant

Biocomposites Ltd
Keele Science Park
Keele
Staffordshire
England
ST5 5NL

Contact Person

Mr Simon Fitzer
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Classification Name:	Screw, fixation, bone
Common/Usual Name:	Bone screw
Trade/Proprietary Name	GraftLok™ Screw GraftLok™ ST Screw
Product Code	HWC
CFR Section	21CFR888.3040

Device Description

The GraftLok™ Screw and GraftLok™ ST Screw are cannulated, sterile, single use bone screw manufactured from poly L-lactic acid (PLLA).

Intended Use / Indications

The GraftLok™ Screw and the GraftLok™ ST Screw have the exact same intended use and indications as the predicate devices.

The GraftLok™ Screw is indicated for use in anterior cruciate ligament (ACL) reconstruction procedures where the surgeon places the graft in tibial and/or femoral tunnels and inserts screws between the tunnel wall and graft to hold the graft in place.

The GraftLok™ Screw is used to provide interference fixation of patellar bone-tendon-bone grafts in ACL reconstruction.

The GraftLok™ Screw is used to provide interference fixation during femoral and/or tibial fixation in ACL reconstruction using a soft tissue graft (semi-tendonosis gracilis).

The GraftLok™ ST Screw is indicated for use in anterior cruciate ligament (ACL) reconstruction procedures. GraftLok™ ST Screw is used to provide suspensary fixation during femoral fixation in ACL reconstruction using double looped (semitendinosis/gracilis) or quadruple (semitendinosis) graft.

Summary of Technology

The GraftLok™ Screw and GraftLok™ ST Screw have the same technological characteristics as the legally marketed predicate devices and any differences do not raise any concerns regarding safety and effectiveness.

Non Clinical Testing

Documentation provided demonstrates that the GraftLok™ Screw and GraftLok™ ST Screw are substantially equivalent to the legally marketed predicate devices and any differences do not raise any concerns regarding safety and effectiveness.

Substantial Equivalence

Documentation provided demonstrates that the GraftLok™ Screw and GraftLok™ ST Screw are substantially equivalent to the legally marketed predicate devices and any differences do not raise any concerns regarding safety and effectiveness.

Safety and Performance

Documentation provided demonstrates that the GraftLok™ Screw and GraftLok™ ST Screw are substantially equivalent to the legally marketed predicate devices and any differences do not raise any concerns regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biocomposites Ltd
% Mr. Simon Fitzer
Keele Science Park
Keele
Staffordshire
England
ST5 5NL

AUG 14 2007

Re: K071952
Trade/Device Name: GraftLok™ Screw and GraftLok™ ST Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, JDR, MAI
Dated: July 9, 2007
Received: July 16, 2007

Dear Mr. Fitzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for MN

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K071952

Device Name: GraftLok™ Screw

Indications For Use:

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The GraftLok™ Screw is used to provide interference fixation during femoral and/or tibial fixation in ACL reconstruction using a soft tissue graft (semi tendonosis gracilis).

Prescription Use ✓ OR Over-The-Counter use No
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071952

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510(k) Number (if known): K071952

Device Name: GraftLok™ ST Screw

Indications For Use:

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The GraftLok™ ST Screw is used to provide suspensary fixation during femoral fixation in ACL reconstruction using double looped (semitendinosis/gracilis) or quadruple (semitendinosis) graft.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) OR Over-The-Counter use NO (Part 21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)